

REMARKS

The Applicants have read the Examiner's Office Action of September 23, 2003 and have the following comments.

*Written Description Requirement*

The pending claims (13-25) have been rejected as allegedly in violation of the written description requirement of 35 USC 112. Applicants respectfully traverse this rejection for the following reasons.

The pending claims are methods for treating protecting ocular neural tissue from damage due to electromagnetic irradiation of the retina by delivering a neuroprotectant to such ocular tissue. The Examiner concedes that the specification discloses structures of particular exemplary neuroprotection compounds. See page 2 of September 23 Office Action. However, the Examiner states

“there is no evidence that there is any *per se* structure/function relationship between the disclosed neuroprotectant compounds and any others that might be found using the claimed method.

Structural identifying characteristics of the group of neuroprotectant compounds are not disclosed. Therefore, the claimed invention is not supported by an adequate written description.”

*Id.*

The present therapeutic method claim is not a “screening” method or otherwise a method such that neuroprotectants “might be found using the claimed method”, as alleged by the Examiner. Rather, it is Applicants’ opinion and position that the terms “neuroprotection” and “neuroprotectant” are well-known terms in the neurobiological arts, and that the person of ordinary skill in the art, armed with an understanding of these terms, combined with the specific examples of exemplary neuroprotectant compounds mentioned in the specification, would understand that the Applicants conceived of and intended to claim (in other words, were “in possession” of) new and non-obvious uses of neuroprotectant compounds. This is consistent with the written description requirement’s purpose, which is to “put the public in possession of what the party claims as his own invention, so as to ascertain if he claims anything that is in common use or is already known. . . .” *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991) (hereinafter *Vas-Cath*).

Federal Circuit case law and the *PTO Final Examiner Guidelines on Written Description Requirement*, 66 Fed. Reg. 1099 (BNA Patent, Trademark and Copyright J., January 12, 2001) (hereinafter the “Guidelines”) are consistent with the Applicants’ view. The Guidelines state that “it is acknowledged that if evidence typically provided to prove a complete conception of the invention is present in the specification as filed, it would be sufficient to show possession.” Guidelines, comment 12, page 1101.

Furthermore, the Guidelines indicate that there is not just a presumption, but a strong presumption, that an adequate written description of the claimed invention is present when the application is filed, and that “an originally filed claim is its own written description”. Guidelines, comment 3. Under the

Guidelines, the “burden is on the Examiner to establish that description as filed is not adequate and . . . to introduce sufficient evidence or technical reasoning to shift the burden” to the Applicant. *Id.*

As a result, it is not the Applicants’ burden to provide evidence that there is an adequate written description. To the contrary, it is the Examiner’s weighty burden to provide evidence which overcomes the “strong presumption” that the claims are supported by adequate written description in the specification – in other words to show that a person of skill in the art would not understand that the Applicants had “possession” or conception of the claimed invention. This, the Examiner has not done.

Nevertheless, for the Examiner’s convenience Applicants herewith enclose a printout from an Internet Yahoo database search of the term “neuroprotective compound” as an illustration that the term is generally known to pertain to compounds that prevent or minimize neuronal cell damage. This search revealed about 466 results. A greater number of results might be expected in a scientific database used by those of skill in the art.

For the above reasons Applicants respectfully request that the Examiner reconsider and withdraw this rejection. Should any fee be due in connection with this communication kindly use Deposit Account 01-0885 for the payment thereof.

Respectfully submitted,



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